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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/811,538 | 03/20/2001 | Mary A. Reppy | 2001/00005 | 9053 |

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 05/07/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/811,538

Applicant(s)

REPPY ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communicati n appears n th cover sheet with the c rresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 20-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. In view of the appeal brief filed on 3/6/03, PROSECUTION IS HEREBY REOPENED.

New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) File a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) Request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

2. Claims 1-46 are pending. Claims 20-46 have been withdrawn from further consideration a being drawn to a non-elected invention.

Election/Restrictions

3. This application contains claims 20-46 drawn to an invention nonelected ***without*** traverse in Paper No. 4. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

4. Claims 1-19 are treated on the merit in this Office Action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The term “polydiacetylene backbone” of claim 1 is vague and indefinite because it is unclear as to what “backbone” is it referring to. The specification (pg. 1, lines 14-15) defines polydiacetylene as conjugated polymers with backbones of alternating double and triple bonds.

b. Claim 9 is vague and indefinite because it is unclear as to further limiting the subject matter of claim 1. Claim 1 recites that a change in fluorescent of the “polydiacetylene” would occurs in the presence of an analyte and claim 9 recites that the “polydiacetylene” is in a “non-fluorescent form”. It is unclear as to the metes and bound of a “non-fluorescent form” (i.e. is it the background fluorescent of the “polydiacetylene” or the absence of the analyte) and is the “polydiacetylene” of claim 9 the same as the “polydiacetylene” of claim 1.

7. Claim 9 recites the limitation "polydiacetylene" in line 1. There is insufficient antecedent basis for this limitation in the claim 1.

8. Claim 9 recites the limitation "non-fluorescent form" in line 2. There is insufficient antecedent basis for this limitation in the claim 1.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-2 and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Reichert et al. (*J. Am. Chem. Soc.*, **1995**, 117:829-830).

The presently claimed claims recite a method for detection of an analyte in a sample. The method comprise of contacting the sample with the three-dimensional array. The three-dimensional array comprise of a polydiacetylene backbone and a substrate, wherein the substrate has direct affinity for an analyte. The polydiacetylene of the array is in the non-fluorescent form.

Reichert et al. disclosed a method of detecting influenza virus (analyte) with functionalized polydiacetylene liposomes (three-dimensional array) (pg. 829, left col., lines 20-27). The functionalized polydiacetylene liposome incorporates both the sialic acid ligand (substrate) for viral binding and the diacetylenic functionality, which is the conjugated backbone of alternating double and triple bonds (pg. 829, left col., lines 29-33), in the hydrocarbon chain for polymerization (pg. 829, right col., lines 1-3). The influenza virus is added to the liposomes in PBS buffer (contacting step), the solution immediately changes to a pink or orange color (the polydiacetylene of the array in a non-fluorescent form) (pg. 829, right col., lines 30-32). These color changes are readily visible with the naked eye and can be quantified by visible absorption

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spectroscopy. Therefore, the method of Reichert et al. anticipates the presently claimed invention.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saul et al. (US Patent 5,415,999) and Charych et al. (US Patent 6,180,135 B1).

The presently claimed claims recite a method for detection of an analyte in a sample. The method comprise of contacting the sample with the three-dimensional array. The three-dimensional array comprise of a polydiacetylene backbone and a substrate, wherein the substrate has direct affinity for an analyte. The change in fluorescent of the polydiacetylene of

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the array is in response to the analyte present in the sample and detecting the change in fluorescence to indicate the presence of an analyte.

Charych et al. disclosed a method for detection of an analyte in a sample comprising a three-dimensional array of a polydiacetylene backbone and the array is in the form of liposomes or tubules (Abstract; col. 4, line 24-33; col. 8, line 63-64). The liposomes comprised of polydiacetylene, which has a conjugated backbone of alternating double and triple bonds (col. 4, lines 25-29), and ligand (col. 10, lines 7-37). The liposomes produced by either of the process of claim 1 or 22 of Charych et al. are the same as those of instant claim 1 with the exception that the array of the instant claim is fluorescent in nature while that of Charych et al. is colorimetric in nature.

The method of Charych et al. differs from the claimed invention in failing to disclose the fluorescent detection of the polydiacetylene backbone.

Saul et al. disclosed a method for detection of an analyte in a sample (Abstract). The method comprises the use of a polydiacetylene backbone (col. 2, line 61-67; claim 1 and 6). A substrate incorporated is in an array (col. 3, line 10-15). The substrate has direct affinity for the analyte or can function as a binder to the analyte or can react with the analyte (claim 1(a), col. 14, line 21-32; col. 3, line 34-39). Detecting the change in fluorescence is used to indicate the presence of the analyte (col. 3, line 25-29; claim 1(b), line 32-33). The analyte is an enzyme, antigen, antibody or antibody fragment and the substrate is a specific binding pair member of the analyte (col. 2, line 44-47; col. 6, line 9-21, and 67-68 and continue to col. 7, line 1-6; col. 10, line 5-24). The substrate includes a ligand (col. 3, line 34-35 and 40-42). The substrate includes

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a reactive substrate (col. 6, line 9-14). The polydiacetylene of the array exhibits fluorescence and the fluorescence increases as an indication of the presence of the analyte (col. 8, line 18-28).

The teaching of both Charych et al. and Saul et al. demonstrate that both colorimetric and fluorescent detection methods are well known for use with analytical methods which use polydiacetylene films (Charych: col. 2, line 59 through col. 3, line 5; Saul: col. 2, line 61-67; claim 1 and 6) it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the *colorimetric* method of detection of the “*polydiacetylene*” of Charych et al. by including the *fluorescent* method of detection of the “*polydiacetylene*” as taught by Saul et al. with the expectation of obtaining an equivalent method of direct detection of small molecules using a three dimensional polymeric assemblies and a test system that can be suspended in fluid or bound to various supports (Charych: col. 3, line 29-39).

Response to Arguments

14. Applicant's arguments with respect to claims 1-19 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
April 21, 2003



ANDREW WANG
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